

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
24-60213-CR-LEIBOWITZ/AUGUSTIN-BIRCH

Case No. _____

18 U.S.C. § 371

18 U.S.C. § 981(a)(1)(C)

UNITED STATES OF AMERICA

vs.

ANGELA BAQUERO and
RICARDO ACUNA,

Defendants.

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times relevant to this Information:

Legal Background

1. Clinical investigations, also known as clinical trials, were research studies conducted on voluntary human subjects designed to answer specific questions about the safety or effectiveness of new drugs. Drug developers, or “sponsors,” initiated and took responsibility for clinical trials.

2. The United States Food and Drug Administration (“FDA”) was responsible for ensuring that drugs intended for human use were safe and effective. The FDA relied on the truthfulness and accuracy of the results of clinical trials to make regulatory decisions about the approval of new drugs with the goal of ensuring that all FDA-approved drugs were safe and effective for their approved uses in humans.

FILED BY mp D.C.

Nov 5, 2024

ANGELA E. NOBLE
CLERK U.S. DIST. CT.
S. D. OF FLA. - Miami

3. Before beginning a clinical trial, sponsors were required to provide the FDA with extensive information regarding the proposed trial, including a detailed investigation plan known as a “study protocol.” The study protocol described, among other things, the eligibility criteria for individuals to enroll as study subjects, schedules of tests and procedures, drug and dosage regimens, the length of the study, and the health outcomes to be measured by the study. Clinical trials were required to be conducted according to the study protocol, as well as applicable laws and FDA regulations.

4. Sponsors generally retained contract research organizations (“CROs”) to oversee and conduct various aspects of clinical trials. Sponsors and CROs typically contracted with multiple research sites to perform clinical trials. Under such an arrangement, each individual clinical trial site was responsible for identifying study subjects, enrolling them into the study, performing the study, gathering data, and reporting the data to the sponsor and/or CRO, in accordance with the study protocol.

5. Each clinical trial site had a clinical investigator, also known as a principal investigator. The clinical investigator was the individual responsible for conducting the clinical investigation at that site and ensuring that the clinical trial was conducted according to the study protocol.

6. The clinical investigator had the authority to delegate certain responsibilities to clinical trial site staff working on the clinical trial, including to clinical research coordinators.

7. The clinical investigator was also required, by regulation, to prepare and maintain records relating to clinical research trials. These records, known as “case histories,” included records of the dispensation of the study drug, including dates and quantities of drugs dispensed to subjects; informed consent forms and medical records for each subject participating in the clinical

research trial; and records of all observations and other data pertinent to the investigation for each subject administered an experimental drug.

8. The FDA had the authority to inspect a clinical investigator to ensure that the clinical investigator was complying with all applicable laws and regulations in conducting clinical trials. The FDA's inspection authority included the authority to review case histories and other records maintained by the clinical investigator.

9. A clinical investigator provided to the sponsor or CRO the information about each study subject enrolled in the study, including his or her medical history, laboratory results, and reaction to the drug under study. The sponsor then provided the information to the FDA for its use in evaluating whether the drug was safe and effective and should be approved for its intended use.

The Defendants and their Co-Conspirators

10. A&R Research Group LLC ("A&R") was a business incorporated in Florida that conducted clinical trials of new drugs for pharmaceutical companies and other sponsors. A&R's principal place of business was on North University Drive in Pembroke Pines in Broward County, Florida.

11. Defendant **ANGELA BAQUERO** resided in Weston, Florida. From in or around November 2009 and continuing through in or around January 2020, **BAQUERO** was a co-owner of A&R and served as A&R's clinical research director and manager, and as a study coordinator.

12. Defendant **RICARDO ACUNA** resided in Weston, Florida. From in or around November 2009 and continuing through in or around January 2020, **ACUNA** was co-owner of A&R and served as A&R's regulatory and contract affairs manager.

13. An individual, hereinafter "Clinical Investigator," was a resident of Hollywood, Florida. Clinical Investigator served as the clinical investigator at A&R for the clinical trials described herein.

14. Co-Conspirator 1, a resident of Miramar, Florida, was enrolled in at least one of the clinical trials at A&R.

15. Co-Conspirator 2, a resident of Miramar, Florida, was enrolled in at least one of the clinical trials at A&R.

The Asthma Trials

16. Beginning in or around January 2019 and continuing through in or around January 2020, A&R, **ANGELA BAQUERO, RICARDO ACUNA**, and Clinical Investigator conducted two clinical trials concerning investigational drugs intended to treat persons suffering from moderate to severe asthma and mild to moderate asthma (hereinafter, the “asthma trials”).

17. The first trial (hereinafter “Asthma Trial 1”) was designed to compare the efficacy and safety of two investigational asthma medications when administered in response to a “severe asthma exacerbation,” commonly referred to as an “asthma attack,” in subjects with moderate to severe asthma.

18. The second trial (hereinafter “Asthma Trial 2”) was designed to assess the efficacy and safety of an investigational asthma medication and its components on the improvement of lung function and asthma symptoms in subjects with mild to moderate asthma.

19. The study protocols for the asthma trials required subjects to meet certain eligibility criteria to qualify for and be enrolled in the trials. To qualify for Asthma Trial 1, among other criteria, the subject had to have received an asthma diagnosis at least one year prior to the subject’s first visit to A&R, and have a documented history of at least one severe asthma exacerbation within one year before the first visit to A&R. To qualify for Asthma Trial 2, among other criteria, the subject had to have received a documented asthma diagnosis in the six months prior to the subject’s first visit to A&R.

20. Once enrolled in one of the asthma trials, the study protocols required the subject to submit to routine clinical procedures and safety measurements, such as a physical examination and check of vital signs, as well as study specific assessments, such as an electrocardiogram (“ECG”) reading, pulmonary function tests (“PFTs”), and the drawing of blood samples for hematology and clinical chemistry. The clinical investigator was required to ensure that the performance of these clinical procedures—including the performance of physical exams—were accurately and adequately documented in the case history for each study subject.

21. According to each of the study protocols, the physical examinations were required to be performed by the clinical investigator or, per the Site Delegation of Authority Log, could be delegated by the clinical investigator to a sub-investigator.

22. Prior to beginning the asthma trials, A&R – through **RICARDO ACUNA** and Clinical Investigator – entered into a Clinical Trial Agreement for each of the asthma trials with the CRO. The CRO entered into the Clinical Trial Agreements with A&R on behalf of the sponsor as the sponsor’s contractor. The Clinical Trial Agreements required, among other things, that Clinical Investigator follow the respective study protocols in conducting the asthma trials.

23. At or around the same time that A&R entered the Clinical Trial Agreements, a Form FDA 1572 for each of the asthma trials – which bore Clinical Investigator’s purported signature – was submitted to the sponsor and indicated that Clinical Investigator agreed to comply with the terms of the study protocol and all applicable FDA regulations.

24. The Clinical Trial Agreements between A&R, Clinical Investigator, and the CRO also included a schedule of payments the sponsor would pay A&R per study subject for each procedure, physical exam, office visit, or other procedure required under the protocol for each asthma trial. For each subject who completed all the required visits in Asthma Trial 1, the Clinical

Trial Agreement required the sponsor to pay A&R \$11,013.04. For each subject who completed all the required visits in Asthma Trial 2, the Clinical Trial Agreement required the sponsor to pay A&R \$11,412.07.

Conspiracy to Commit Wire Fraud
(18 U.S.C. § 371)

Beginning in or around January 2019, and continuing through in or around January 2020, in Broward County, in the Southern District of Florida, and elsewhere, the defendants,

ANGELA BAQUERO and
RICARDO ACUNA,

did willfully, that is, with the intent to further the object of the conspiracy, and knowingly combine, conspire, confederate, and agree with each other and with others known and unknown to the United States Attorney to defraud the sponsor by knowingly, and with the intent to defraud, devising and intending to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that the pretenses, representations, and promises were false and fraudulent when made, and, for the purpose of executing the scheme and artifice, did transmit and cause to be transmitted by means of wire communication in interstate and foreign commerce, certain writings, signs, signals, pictures, and sounds, in violation of Title 18, United States Code, Section 1343.

Purpose of the Conspiracy

25. It was the purpose of the conspiracy for the defendants and their co-conspirators to unlawfully enrich themselves by, among other things: (a) securing contracts to conduct the asthma trials; (b) fabricating and falsifying documents, study data, and other items related to the asthma trials to obtain payments and inflate the payments due under the Clinical Trial Agreements; (c) concealing from the FDA, the sponsor, and the CRO the fact that subject eligibility for and

participation in the asthma trials had been falsified and fabricated; (d) receiving payment for the asthma trials by making materially false and fraudulent representations about the trials; and (e) using the fraudulently obtained funds for the defendants' personal use and benefit, the use and benefit of others, and to further the conspiracy.

Manner and Means of the Conspiracy

The manner and means by which the defendants and their co-conspirators sought to accomplish the object and purpose of the conspiracy included, among other things, the following:

26. **ANGELA BAQUERO**, Co-Conspirator 1, and Co-Conspirator 2 obtained false and fraudulent medical records for at least seventeen individuals so that **BAQUERO** could enroll those individuals as subjects in the asthma trials, despite the individuals not having the legitimate documented asthma diagnosis needed to qualify for and participate in the asthma trials.

27. **ANGELA BAQUERO** enrolled subjects in the asthma trials who did not satisfy the eligibility criteria required for enrollment and participation in the trials to inflate the payments received from the sponsor under the Clinical Trial Agreements.

28. **ANGELA BAQUERO** obtained false and fraudulent study assessments and blood samples for certain subjects to conceal the fact that those subjects enrolled in the asthma trials were not qualified for and were not participating in the trials.

29. **RICARDO ACUNA** paid Co-Conspirator 1 and Co-Conspirator 2 to perform the PFTs and ECGs for certain third parties enrolled as subjects in the asthma trials, and **ANGELA BAQUERO** falsely portrayed the PFT results and ECG readings as the readings and results of those third parties. In some instances, **BAQUERO** drew blood from Co-Conspirator 1 and Co-Conspirator 2 and falsely portrayed the blood samples as having been drawn from third parties enrolled as subjects in the asthma trials.

30. In furtherance of the conspiracy, **ANGELA BAQUERO** performed a PFT on herself, and falsely portrayed the PFT results as those of a third party enrolled as a subject in the asthma trials.

31. **ANGELA BAQUERO** and the Clinical Investigator created false and fraudulent case histories in the asthma trials to make it appear as if A&R and the Clinical Investigator were fulfilling their responsibilities under the Clinical Trial Agreements and complying with the asthma trial protocols, when in fact they were not.

32. As part of their effort to conceal the fact that A&R falsified asthma trial data, **ANGELA BAQUERO** and **RICARDO ACUNA** knowingly provided false information to the sponsor, the CRO, and the FDA.

33. As a result of the false and fraudulent representations made by **ANGELA BAQUERO**, **RICARDO ACUNA**, and their co-conspirators, the sponsor paid A&R to conduct the asthma trials via interstate wire communications.

34. **ANGELA BAQUERO**, **RICARDO ACUNA**, and their co-conspirators used the funds for their personal use and benefit, the use and benefit of others, and to further the conspiracy.

Overt Acts

In furtherance of the conspiracy, and to accomplish the object and purpose thereof, at least one of the following overt acts, among others, were committed in the Southern District of Florida, and elsewhere, by at least one co-conspirator:

1. On or about January 18, 2019, Clinical Investigator and **RICARDO ACUNA** signed their names to a Clinical Trial Agreement with the CRO, whereby **ACUNA**, acting on behalf of A&R, and Clinical Investigator agreed to serve as a trial site and clinical investigator, respectively, for Asthma Trial 1.

2. On or about February 26, 2019, Clinical Investigator and **RICARDO ACUNA** signed their names to a Clinical Trial Agreement with the CRO, whereby **ACUNA**, acting on behalf of A&R, and Clinical Investigator agreed to serve as a trial site and clinical investigator, respectively, for Asthma Trial 2.

3. On or about March 4, 2019, **ANGELA BAQUERO** performed a PFT on herself at A&R, and falsely portrayed the PFT results as those of a third party enrolled as a subject in Asthma Trial 1.

4. On or about March 8, 2019, **ANGELA BAQUERO** initialed Co-Conspirator 1's medical release authorization form and wrote, "Patient brough [*sic*] medical records," indicating that **BAQUERO** was accepting Co-Conspirator 1's medical records for Asthma Trial 1, when, in fact, **BAQUERO** knew that Co-Conspirator 1 had provided false and fraudulent medical records for Asthma Trial 1.

5. On or about March 8, 2019, **ANGELA BAQUERO** signed and dated the inclusion and exclusion criteria list for Co-Conspirator 1 that falsely indicated that Co-Conspirator 1 satisfied the asthma diagnosis requirement for Asthma Trial 1 and falsely indicated that Co-Conspirator 1 was not concurrently enrolled in any other clinical trials.

6. On or about March 22, 2019, **ANGELA BAQUERO** enrolled Co-Conspirator 1 in Asthma Trial 1 despite the fact that **BAQUERO** knew that Co-Conspirator 1 had not provided legitimate proof of a qualifying asthma diagnosis, had enrolled in Asthma Trial 1 under a false identity using a fake driver's license, and was concurrently enrolled in a different clinical trial at A&R.

7. On or about May 28, 2019, **RICARDO ACUNA** signed and issued a check on behalf of A&R for \$150 to Co-Conspirator 2 for “4 Spirometries,” which **ACUNA** knew was to pay for Co-Conspirator 2 having performed the spirometry test on behalf of other subjects.

8. On or about June 12, 2019, **RICARDO ACUNA** signed and issued a check on behalf of A&R for \$120 to Co-Conspirator 1 for “Med Recs DS & GP,” which **ACUNA** knew was to pay Co-Conspirator 1 for bringing in false and fraudulent medical records on behalf of other subjects.

9. On or about June 25, 2019, **RICARDO ACUNA** signed and issued a check on behalf of A&R for \$80 to Co-Conspirator 2 for “2 Espirometrias,” which **ACUNA** knew was to pay for Co-Conspirator 2 having performed the spirometry test on behalf of other subjects.

10. On or about September 17, 2019, **ANGELA BAQUERO** sent the sponsor via email a document, signed by **BAQUERO** and **RICARDO ACUNA**, in which **BAQUERO** and **ACUNA** provided false reasons for why different study subjects had similar PFT and ECG readings.

11. On or about January 24, 2020, during the course of an FDA inspection, **ANGELA BAQUERO** provided the FDA investigator with case histories, which **BAQUERO** and **RICARDO ACUNA** knew contained false and fraudulent medical records.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATIONS
(18 U.S.C. § 981(a)(1)(C))

35. The allegations of this Information are hereby re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America of certain property in which the defendants, **ANGELA BAQUERO** and **RICARDO ACUNA**, have an interest.


36. Upon conviction of a violation of, or a conspiracy to violate, Title 18, United States Code, Section 371, specifically to commit a violation of Title 18, United States Code, Section 1343, as alleged in this Information, the defendants shall forfeit to the United States any property, real or personal, which constitutes or is derived from proceeds traceable to such offense, pursuant to Title 18, United States Code, Section 981(a)(1)(C).

37. If any of the property described above, as a result of any act or omission of the defendants:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,


the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), and the procedures set forth in Title 21, United States Code, Section 853, as incorporated by Title 28, United States Code, Section 2461(c).



MARKENZY LAPOINTE
UNITED STATES ATTORNEY

AMANDA LISKAMM
DIRECTOR
U.S. DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH

By: 

For ANDREW K. CRAWFORD
BRIANNA M. GARDNER
TRIAL ATTORNEYS
U.S. DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH

CASE NO.: 24-60213-CR-LEIBOWITZ/AUGUSTIN-BIRCH

CERTIFICATE OF TRIAL ATTORNEY

Total number of new counts _____

Court ID No. A5502885

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: RICARDO ACUNA

Case No: _____

Count #: 1

Title 18, United States Code, Section 371

Conspiracy to Commit Wire Fraud

* Max. Term of Imprisonment: 5 years

* Mandatory Min. Term of Imprisonment (if applicable): N/A

* Max. Supervised Release: 3 years

* Max. Fine: \$250,000 or twice the gross gain or loss from the offense

*Refers only to possible term of incarceration, supervised release and fines. It does not include restitution, special assessments, parole terms, or forfeitures that may be applicable.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: ANGELA BACQUERA

Case No: _____

Count #: 1

Title 18, United States Code, Section 371

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AO 455 (Rev. 01/09) Waiver of an Indictment

UNITED STATES DISTRICT COURT

for the
Southern District of Florida

United States of America

v.

Angela Baquero,

Defendant

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)

Case No.

24-60213-CR-LEIBOWITZ/AUGUSTIN-BIRCH

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

After receiving this advice, I waive my right to prosecution by indictment and consent to prosecution by information.

Date: _____

Defendant's signature

Signature of defendant's attorney

Printed name of defendant's attorney

Judge's signature

Judge's printed name and title

AO 455 (Rev. 01/09) Waiver of an Indictment

UNITED STATES DISTRICT COURT

for the
Southern District of Florida

United States of America

v.

Ricardo Acuna,

Defendant

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)

Case No.

24-60213-CR-LEIBOWITZ/AUGUSTIN-BIRCH

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Date: _____

Defendant's signature

Signature of defendant's attorney

Printed name of defendant's attorney

Judge's signature

Judge's printed name and title